containing approximately 500 milligrams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Place an accurately measured representative portion of the suspension into an appropriate-sized volumetric flask and dilute to volume with 0.1*M* potassium phosphate buffer, pH 4.5 (solution 4). Further dilute an aliquot of the stock solution with solution 4 to the reference concentration of 10 micrograms of cephaloglycin per milliliter (estimated).

(2) *Moisture*. Proceed as directed in §436.201 of this chapter.

(3) *pH*. Proceed as directed in §436.202 of this chapter, using the drug reconstituted as directed in the labeling.

(4) *Identity*. Dilute a representative portion of the sample with sufficient distilled water to give a concentration of 2.5 milligrams of cephaloglycin per milliliter (estimated). Shake vigorously on a mechanical shaker for 30 minutes. Filter through Whatman No. 1 filter paper, discarding the first few milliliters of filtrate. Further dilute an aliquot of the filtrate with sufficient distilled water to give a concentration of 0.05 milligram of cephaloglycin per milliliter (estimated). Using a suitable spectrophotometer, record the ultraviolet absorption spectrum of this solution from 230 to 320 nanometers. The spectrum compares qualitatively to that of the cephaloglycin working standard similarly treated.

[39 FR 19040, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§442.127 Cephalexin monohydrate oral dosage forms.

§442.127a Cephalexin monohydrate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Cephalexin monohydrate tablets are composed of cephalexin monohydrate and one or more suitable and harmless diluents, binders, lubricants, colorings, and coating substances. Each tablet contains cephalexin monohydrate equivalent to 250, 500, or 1,000 milligrams of cephalexin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalexin that it is represented to contain. Its moisture content is not more than 9 percent. The tablets disintegrate within 30 minutes. The cephalexin monohydrate used conforms to the standards prescribed by §442.27(a)(1).

(2) *Labeling*. It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples*. In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephalexin monohydrate used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The cephalexin monohydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency*. Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay*. Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute with solution 1 to the reference concentration of 20.0 micrograms of cephalexin per milliliter (estimated).

(ii) *Iodometric assay*. Proceed as directed in §436.204 of this chapter, preparing the sample as follows: Blend a representative number of tablets in a high-speed glass blender with sufficient distilled water to give a stock solution of convenient concentration. Further

dilute with distilled water to the prescribed concentration of cephalexin.

NOTE: The 10.0 milliliters of 0.01*N* iodine must be added within 20 seconds after the addition of the 2.0 milliliters of 1.2*N* hydrochloric acid, and the assay should be completed within 1 hour after the sample and standard are first put into solution.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section.

[39 FR 19040, May 30, 1974, as amended at 40 FR 49083, Oct. 21, 1975; 50 FR 19919, May 13, 1985; 52 FR 20710, June 3, 1987]

§ 442.127b Cephalexin monohydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephalexin monohydrate capsules are composed of cephalexin monohydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains cephalexin monohydrate equivalent to either 125, 250, or 500 milligrams of cephalexin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalexin that it is represented to contain. Its moisture content is not more than 10 percent. The cephalexin monohydrate used conforms to the standards prescribed by § 442.27(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephalexin monohydrate used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The cephalexin monohydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 20.0 micrograms of cephalexin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Blend a representative number of capsules in a high-speed glass blender with sufficient distilled water to give a stock solution of convenient concentration. Further dilute with distilled water to the prescribed concentration of cephalexin.

NOTE: The 10.0 milliliters of 0.01*N* iodine must be added within 20 seconds after the addition of the 2.0 milliliters of 1.2*N* hydrochloric acid, and the assay should be completed within 1 hour after the sample and standard are first put into solution.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19040, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 442.127c Cephalexin monohydrate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephalexin monohydrate for oral suspension is cephalexin monohydrate with one or more suitable and harmless diluents, buffer substances, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains cephalexin monohydrate equivalent to 25 milligrams, 50 milligrams, or 100 milligrams of cephalexin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalexin that it is represented to contain. Its moisture content is not